

Urgent: Product Recall – Retail Level

July 15, 2015

Subject: RECALL OF CERTAIN LOT NUMBERS OF **SENSODYNE® Repair & Protect, SENSODYNE® Complete and BIOTENE® Gel and Toothpaste**

Dear GSK Customer:

GSK Consumer Healthcare is conducting a voluntary retail-level recall of
ONLY THE LOT NUMBERS IN THE ATTACHMENT
of the following **SENSODYNE® Repair & Protect, SENSODYNE® Complete**
and BIOTENE® Gel and Toothpaste products:

- Sensodyne® Repair & Protect Toothpaste
- Sensodyne® Repair & Protect Extra Fresh Toothpaste
- Sensodyne® Complete Toothpaste
- Sensodyne® Complete Extra Fresh Toothpaste
- Biotene® PBF Toothpaste (Plaque Bio-Film Dissolving Formula)
- Biotene® Gentle Mint Gel
- Biotene® Gentle Mint Toothpaste
- Biotene® Fresh Mint Original Toothpaste

The product is being recalled as a precautionary measure because it may contain wood fragments. GSK Consumer Relations received a small number of complaints on product which was manufactured in 2013 through September 2014 for GSK by a third party contract manufacturer. No injuries have been associated with the use of these products. These products and lot numbers shipped from June 2013 to April 2015.

No other SENSODYNE® Repair & Protect, SENSODYNE® Complete and BIOTENE® Gel and Toothpaste products or lot numbers are affected.

This recall is being conducted with the knowledge of the Food and Drug Administration.

Please immediately examine your inventory, quarantine and cease distribution of all listed lots of affected product. Please carry out a physical count and record this data on the Business Reply Card and the Packing Slip which are included with this letter. The lot number can be found on the end flap of the carton.

Please return all units of the listed lots along with the Packing Slip using the enclosed UPS Return Label to:

GlaxoSmithKline, c/o Stericycle
2670 Executive Drive, Suite A
Indianapolis, IN 46241.

For shipping assistance or questions about the recall process, please contact Stericycle at 1-877-650-3477.



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NDC Number	ITEM	DESCRIPTION	SIZE	LOT NUMBER
0135-0558-01	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3E211
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3G231
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3G251
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3J231
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3N171
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y3N191
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y4A141
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y4C271
	10065	Biotene Gentle Mint Paste	4.3 OZ	Y4E131
	10065A	Biotene Gentle Mint Paste	4.3 OZ	Y4G101
	10065A	Biotene Gentle Mint Paste	4.3 OZ	Y4H191



NDC Number	ITEM	DESCRIPTION	SIZE	LOT NUMBER
0135-0557-02	10052	Biotene Fresh Mint Original	0.70 OZ	X3G121
	10052	Biotene Fresh Mint Original	0.70 OZ	X3H141
	10052	Biotene Fresh Mint Original	0.70 OZ	X3K121
	10052	Biotene Fresh Mint Original	0.70 OZ	X4D281
	10052	Biotene Fresh Mint Original	0.70 OZ	X4G181



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AFFECTED BIOTENE ITEM AND LOT NUMBERS

NDC Number	ITEM	DESCRIPTION	SIZE	LOT NUMBER
0135-0488-01	00320B	Biotene Gentle Mint Gel	4.5 OZ	Y2J101
	00320B	Biotene Gentle Mint Gel	4.5 OZ	Y2J111
	00320B	Biotene Gentle Mint Gel	4.5 OZ	Y3D031



NDC Number	ITEM	DESCRIPTION	SIZE	LOT NUMBER
0135-0557-01	10050	Biotene Fresh Mint Paste	4.3 OZ	X3F032
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3G101
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3G131
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3H171
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3H211
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3H291
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3J271
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3K021
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3K171
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3K291
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3M121
	10050	Biotene Fresh Mint Paste	4.3 OZ	X3N171
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4B061
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4B081
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4C121
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4C251
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4D291
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4D301
	10050	Biotene Fresh Mint Paste	4.3 OZ	X4E081
0135-0557-01	10050A	Biotene Fresh Mint Paste	4.3 OZ	X4G131
	10050A	Biotene Fresh Mint Paste	4.3 OZ	X4H111